DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEB 27 1998

Mr. Richard Kriozere
President
Digi-Trax
1550 Barclay Blvd.
Buffalo Grove, IL 60089

Reference:	BK970013
Product:	DONOR-ID, version 1.0
Date Received:	October 31, 1997
Classification:	Unclassified

Dear Mr. Kriozere:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and have determined that the device is substantially equivalent either to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to a legally marketed predicate device cleared by FDA after that date. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act that include requirements for registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Although your device has been determined to be "substantially equivalent", there are deficiencies in documentation that should be addressed before submitting a future premarket notification for this or a similar device. We are including suggestions for improvement for your consideration as you modify or upgrade this software package or design additional software. For future guidance, please refer to "Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software", dated January 13, 1997.

Our suggestions for future submissions are as follows:

1. When responding to a letter requesting additional information, do not submit a completely revised 510(k), as such a submission necessitates a complete review. Please submit only the response to the stated question, referencing where the supporting information can be found in the submitted material.

2. Your design plan for accommodating the year 2000 describes only a change to the birth year field. Please note that all date fields, e.g., donation date, etc., will require a change in design.

3. The device master record and the device history record should be maintained as two separate records in accordance with 21 CFR 820.181 and 820.184 respectively. Your SOP 0403, "Device Master History Record" should be revised accordingly.

If your device has been classified into either class II (Special Controls) or class III (Premarket Approval), (see above), it may be subject to the above and additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note that this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

An FDA finding of substantial equivalence of your device to a legally marketed predicate device permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on promotional labeling and advertisement for your device, please contact our Advertising and Promotional Labeling Staff at (301) 827-3028.

Sincerely,

Jay S. Epstein, M.D.
Director
Office of Blood Research and Review
Center for Biologics
Evaluation and Research